K041213

JUL 22 2004

SECTION 6 – 510(k) SUMMARY

[Submitted pursuant to 21 CFR 807.87(h)]

1. Submitter Information

Submitter:	Direx Systems Corporation 11 Mercer Road Natick Business Park Natick, MA 01760
Telephone: Fax: Contact Person	(508) 651-0900 (508) 651-8125 Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	*3Dscope.*
Classification Name:	System, x-ray, fluoroscopic, image-intensified.
Classification Name/ Product code:	90 JAA
Regulatory Class:	Class II
Regulation Number:	21 CFR 892.1650

3. Predicate Device

Digiscope RX-2 (9" option) K965013

4. Intended Use

The *3Dscope* is a mobile apparatus used for fluoroscopic examination of a patient.

5. Device Description

The *3Dscope* is a compact, mobile fluoroscopic system designed for general fluoroscopic imaging. *The 3Dscope* acquires, processes, displays, and stores x-ray images, for image diagnosis.

6. Performance Testing

The *3Dscope* conforms to the following standards:

IEC 60601-1 (1998) + A1(1991) + A2(1995)

IEC 60601-1-1 (2000)

IEC 60601-1-2 (2001)

IEC 60601-1-3 (1994)

IEC 60601-2-7 (1998)

IEC 60601-1-4 (2000)

ISO 14971 (2000)

FDA CDRH 21CFR 1020.30

FDA CDRH 21CFR 1020.32

7. Conclusion

The *3Dscope* meets the requirements for a special 510(k) by the virtue of being a minor modification, which does not change the intended use, fundamental technology or reduce safety and effectiveness, of the Company's predicate device, the *Digiscope RX-2 (9" option).*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Larisa Gershtein
QA Manager
DiREX Systems Corporation
11 Mercer Road
MATICK MA 01760

AUG 23 2013

Re: K041213
Trade/Device Name: 3Dscope
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO
Dated: June 22, 2004
Received: June 24, 2004

Dear Ms. Gershtein:

This letter corrects our substantially equivalent letter of July 22, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

DiREX
SYSTEMS CORP.

Attachment 4-1

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K041213

Device Name:

3Dscope

Indications for Use:

The *3Dscope* is a mobile apparatus used for fluoroscopic examination of a patient.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

510(k) Number ✓K041213

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR § 801.109)

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041213

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